UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875**
THIS DOCUMENT RELATES TO: *Roberts v. Zhejiang Huahai Pharmaceutical Co. Ltd.,* Case No. 1:20-cv-00946-RMB-SAK	**HON. RENÉE MARIE BUMB**

PLAINTIFFS' BRIEF IN SUPPORT OF DAUBERT MOTION TO EXCLUDE DEFENSE EXPERT VICTORIA CHERNYAK, M.D., M.S.

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INTRODUCTION

Plaintiffs respectfully move to exclude the testimony of defense expert radiologist, Victoria Chernyak, M.D., M.S., pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Dr. Chernyak, among other factors, reiled on non-existent imaging, did not review any records concerning Mr. Roberts' clinic history, admits she cannot offer an opinion to a medical degree of certainty, and used AI to come to her conclusion that Mr. Roberts might have had liver cancer prior to be exposed to NDMA-contaminated valsartan.

In April of 2016, Mr. Roberts underwent multiple imaging studies of his liver due to a fatty liver.[1] In September of 2016, Mr. Roberts filled his first prescription of NDMA-contaminated valsartan-HCTZ 320-25mg. Then in August of 2018, imaging revealed multiple spots of liver cancer (hepatocellular carcinoma – HCC) greater than 5cm in diameter. Despite all evidence to the contrary, Defendant has decided to defend this case by concluding that Mr. Roberts must have had liver cancer prior to be exposed to NDMA-contaminated valsartan. All of the opinions within Dr. Chernyak's expert report are given in an attempt to provide support for that predetermined, litigation-driven conclusion.

[1] Dr. Chernyak's report (Ex. A), which defense's expert hepatologist (Dr. Mahmud) relied on, inaccurately claims Mr. Roberts underwent an MRI in 2016 (Ex. B - Chernyak Dep. 22:17-25:23) and that Dr. Chernyak can see a lesion on the non-existent 2016 MRI (Chernyak Report at 9).

Based only on a review of Mr. Roberts' imaging studies, Dr. Chernyak opined that Mr. Roberts had cirrhosis in 2016, that certain liver lesions seen on CT and non-existant MRI imaging met the criteria for LI-RADS (Liver Imaging Reporting and Data System) category LR-3 (indeterminate observation), and that one of those lesions may have progressed to liver cancer by 2018. Dr. Chernyak further concludes that cirrhosis, rather than NDMA exposure, was the most likely cause of Mr. Roberts' liver cancer. However, Dr. Chernyak did not review Mr. Roberts' medical records, assess his risk factors, research NDMA, or consider Mr. Roberts' cumulative NDMA exposure. Dr. Chernyak also relied on inapplicable literature, unsupported assumptions, and non-peer-reviewed sources (artificial intelligence) to give an opinion on how Mr. Roberts' tumor might have potentially grown over time in an attempt to support her ultimate conclusion that Mr. Roberts might have had cancer prior to being exposed to NDMA-contaminated valsartan.[2]

The heart of Dr. Chernyak's opinon, that Mr. Roberts had LI-RADS category LR-3 observations in his liver in 2016, is based on a flawed methodology counter to her own published literature on how to apply LI-RADS and the current LI-RADS guidance document. Dr. Chernyak admitted that Mr. Roberts' 2016 CT lacked the required imaging necessary to apply LI-RADS.[3] The remainder of Dr. Chernyak's

[2] Chernyak Report at 8.
[3] Chernyak Dep. 261:2-9.

opinons, such as the rate at which Mr. Roberts' tumor might have grown and the cause of Mr. Roberts' liver cancer, are without a reliable basis and are outside the scope of Dr. Chernyak's expertise as a radiologist. As such, Dr. Chernyak should be exclued from testifying at trial.

APPLICABLE LAW

Rule 702 and *Daubert* Standards

Expert testimony is admissible only if it is both reliable and relevant, as required by Federal Rule of Evidence 702. Under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the trial court serves a "gatekeeping" function to ensure that expert testimony is "not only relevant, but reliable." *Id.* at 589. The Third Circuit has emphasized that *Daubert*'s reliability requirement applies to both the methodology employed by the expert and the manner in which that methodology is applied. See *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 800 (3d Cir. 2017) (affirming exclusion of expert who "failed to consistently apply the scientific methods [he] articulate[d]" and "inconsistently applied methods and standards to the data so as to support [his] a priori opinion"). Courts must ensure "that the testimony given to the jury is reliable and will be more informative than confusing." *Id.*

In assessing whether an expert's testimony is reliable, courts in this Circuit apply the factors set forth in *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717 (3d

Cir. 1994), which include: (1) whether the methodology can be tested; (2) whether it has been subject to peer review; (3) the known or potential error rate; (4) the existence and maintenance of standards; (5) whether the methodology is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put. See *Id.* at 742 n.8. *Paoli* also recognizes that a court must exclude an expert's testimony if *any step* in the expert's reasoning or methodology renders the analysis unreliable. *Id.* at 745. Thus, even where an expert purports to use an accepted methodology, a court must exclude the opinion if the methodology is applied improperly or inconsistently. See *Id.* at 742–45. Further, "the Court should exclude an expert's opinion where a methodological flaw is 'large enough that the expert lacks 'good grounds' for his or her conclusions'." *Freedom Mortg. Corp. v. LoanCare, LLC*, No. CV1602569RMBAMD, 2023 WL 2570201, at *4 (D.N.J. Mar. 20, 2023) (*citing In re Paoli R.R. Yard PDB Litig.*, 35 F3d 717, 746 (3d Cir. 1994).

This requirement of intellectual rigor is especially critical where the expert purports to rely on experience rather than empirical data. As the Third Circuit has explained, "[t]he expert must employ in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Elcock v. Kmart Corp.*, 233 F.3d 734, 746 (3d Cir. 2000) (quoting *Kumho Tire Co. v.*

Carmichael, 526 U.S. 137, 152 (1990)). An expert who departs from the norms of their discipline in litigation cannot offer admissible opinions under Rule 702. Additionally, in *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 Supp. 2d 584 (D.N.J. 2002), aff'd, 68 F. App'x 356 (3d Cir. 2003), the court excluded expert testimony where the expert's conclusions were not the result of research conducted independent of litigation and the expert failed to adequately account for alternative explanations. The court emphasized that unjustified extrapolation from accepted premises to unsupported conclusions is a hallmark of unreliable testimony. *Id.* at 594–95.

The expert testimony must also "fit" the case. *Daubert*, 509 at 592. The "helpfulness" standard requires there to a "valid scientific connection to the pertinent inquiry as a precondition to admissibility". *Id*. at 591-592. In order for the case to "fit" it must assist the trier of fact. *Oddi*, 234 F.3d at 145-146.

FRCP 26(a)(2)

Federal Rule of Civil Procedure 26(a)(2) governs the disclosure of expert testimony, including the specific requirements for expert reports. Under this rule, "[t]he report must contain: (i) a complete statement of all opinions the witness will express and the basis and reasons for them; (ii) the facts or data considered by the witness in forming them …." Fed. R. Civ. P. 26(a)(2)(B)(i) & (ii). Failure to comply with these requirements provides an independent ground for excluding the expert's

testimony. As the Seventh Circuit has explained, "[t]he consequence of non-compliance with Rule 26(a)(2)(B) is exclusion of an expert's testimony[.]" *Meyers v. N'l R.R. Passenger Corp. (Amtrak)*, 619 F.3d 729, 734 (7th Cir. 2010) (internal quotations and citations omitted).

ARGUMENT

I. Mr. Roberts Lacked the Requisite Underlying Diagnosis for Dr. Chernyak to Apply LI-RADS to Mr. Roberts' 2016 CT

Dr. Chernyak's application of the LI-RADS classification system to Mr. Roberts' 2016 CT scan is improper and lacks the methodological reliability required under *Daubert* and Rule 702. According to her own expert report, "the LI-RADS criteria are applied to a restricted patient population with sufficiently high risk for HCC development, namely patients with cirrhosis, chronic hepatitis B viral infection (with or without cirrhosis) and/or personal history of HCC. Diagnosis of cirrhosis … is sufficient to allow application of LI-RADS."[4] However, Dr. Chernyak admitted during her deposition that she did not review any medical records concerning Mr. Roberts' clinical history and was only aware Mr. Roberts had fatty liver disease.[5] Dr. Chernyak admitted that Mr. Roberts did not have hepatitis B[6], but was unsure if Mr. Roberts had been diagnosis with cirrhosis as of the time of his 2016 CT.[7]

[4] Chernyak Report at 2-3; *See also* Chernyak Dep. 120:12-20.
[5] Chernyak Dep. 16:07-16:23.
[6] Chernyak Dep 29:10-13.
[7] Chernyak Dep. 30:22-31:1.

Both Dr. Mahmud (defense's expert hepatologist) and Dr. Siddiqui (plaintiffs' expert oncologist) opined that diagnosing cirrhosis takes both radiological changes and physical symptoms or markers.[8] Dr. Chernyak relied on Dr. Siddiqui's (plaintiffs' oncology expert) opinion that Mr. Roberts had no symptoms[9], yet ignored Dr. Siddiqui's opinion that Mr. Roberts didn't have cirrhosis[10], and instead applied LI-Rads anyway to Mr. Roberts' 2016 CT based solely on her impression of morphologic features consistent with cirrhosis on Mr. Roberts' 2016 CT. Furthermore, Dr. Chernyak conceded that as a radiologist she does not diagnose cirrhosis, but merely "provides things like – statements like morphologic features consistent with cirrhosis".[11] Dr. Chernyak should be precluded from opining that Mr. Roberts had cirrhosis as of 2016, because Dr. Chernyak ignored Mr. Roberts' lack of symptoms and Dr. Chernyak does not diagnose cirrhosis in practice as a radiologist. Dr. Chernyak's application of LI-RADS to Mr. Roberts' 2016 CT, at a time when Mr. Roberts had not been diagnosed with hepatitis B or cirrhosis, is methodologically unsound, is conclusion-driven, and should be excluded.

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[8] Ex. C - Mahmud Dep. 123:13-124:7, 192:13-19; Ex. D - Siddiqui Dep. 193:17-23, 244:7-11, 317:16-20.
[9] Chernyak Dep. 223:14-224:13.
[10] Siddiqui Report at 30 ("I would not have given him an actual diagnosis of cirrhosis at this time.").
[11] Chernyak Dep. 30:9-15.

II. Dr. Chernyak Did Not Rule Out Congenital or Genetic Causes for Mr. Roberts' Undiagnosed Cirrhosis Before Applying LI-RADS to Mr. Roberts' 2016 CT

LI-RADS can not be applied to patients with cirrhosis due to congenital or genetic causes. Dr. Chernyak did not review Mr. Roberts' medical records or adequately rule out congenital or genetic causes for the cirrhosis that Dr. Chernyak claims Mr. Roberts had in 2016.[12] Instead, Dr. Chernyak relied on Dr. Siddiqui's (plaintiffs' expert oncologist) opinion that Mr. Roberts was asymptomatic in 2016 as a basis to rule out Mr. Roberts having liver issues prior to his 18th birthday.[13] When asked if it would have been appropriate to apply LI-RADS if Mr. Roberts was having liver problems before he was 18, Dr. Chernyak answered, "But he wasn't."[14] However, emphasized and bolded in Dr. Mahmud's (defense's expert hepatologist) report is a statement that reads, "**ever since he was a teenager**… **his liver numbers were high.**"[15] While defense expert Dr. Mahmud reviewed and relied on Dr. Chernyak's report, Dr. Chernyak did not review Dr. Mahmud's report.[16] Bolded in Dr. Mahmud's report is that Mr. Roberts' liver numbers were high ever since he was a teenager.

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[12] Chernyak Dep. 222:13-223:12, 16:07-16:23.
[13] Chernyak Dep. 223:14-224:13.
[14] Chernyak Dep. 224:14-19.
[15] Mahmud Report at 6, 20.
[16] Chernyak Dep. 225:19-226:4.

Mr. Roberts' liver issues existing from the time of adolescence should have precluded Dr. Chernyak from applying LI-RADS to Mr. Roberts' 2016 CT. Furthermore, Dr. Chernyak's lack of adherence to the LI-RADS' methodology by not investigating whether Mr. Roberts had congenital or genetic explanations for his alleged cirrhosis is evidence of a conclusion driven expert report.

III. Mr. Roberts' 2016 CT Lacked the Required Phases to Apply LI-RADS

Dr. Chernyak testified that in order to apply LI-RADS to a CT image, there are three required phases: arterial phase, portal venous phase, and delayed phase.[17] Dr. Chernyak's testimony was consistent with her own publication requiring all three phases to apply LI-RADS.[18] Dr. Chernyak's testimony was also consistent with the most current LI-RADS CORE guidance document, which explicitly requires arterial, portal venous, and delayed phases to apply LI-RADS to a CT.[19] Dr. Chernyak explained that if all three phases aren't obtained, you can't apply LI-RADS.[20] When asked if one of the three phases was more important, Dr. Chernyak testified, "You need all three to make LI-RADS."[21] In fact, Dr. Chernyak testified that she could not apply LI-RADS to Mr. Roberts 2018 CT, because it lacked the required phases.[22]

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[17] Chernyak Dep. 171:14-22, 250:17-251:11.
[18] Chernyak Dep. 157:17-19, 171:14-22.
[19] Chernyak Dep. 241:10-13, 270:1-4.
[20] Chernyak Dep. 67:11-14.
[21] Chernyak Dep. 174:16-20.
[22] Chernyak Dep. 65:21-67:14.

Dr. Chernyak incorrectly believed that Mr. Roberts' 2016 CT, "was done with appropriate required protocol with and without contrast with arterial phase, portal venous phase and delayed."[23] However, after reviewing Mr. Roberts' 2016 CT during her deposition, Dr. Chernyak repeatedly conceded that Mr. Roberts' 2016 CT was also missing the required delayed phase necessary to apply LI-RADS:[24]

Q. So there was no delayed phase in this [2016] CT, was there?
A. There was no delayed phase on the CT.
Q. And the LI-RADS 2018 CORE says that is a required phase, the delayed phase, doesn't it?
A. It does.

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Q. And the 2018 LI-RADS CORE lists a required image as the delayed phase; correct?
A. It – yes.
Q. And you did not have a delayed phase with Mr. Roberts; correct?
A. Correct.

Even if Dr. Chernyak could apply LI-RADS to a patient that had not been diagnosed with hepatitis B or cirrhosis, Dr. Chernyak lacked the required imaging phases to apply LI-RADS to Mr. Roberts' 2016 CT.

IV. Dr. Chernyak Failed to Consider All LI-RADS Categories

Dr. Chernyak states in her expert report that, "Diagnostic LI-RADS includes ***seven*** diagnostic categories, each representing a diagnostic certainty of HCC vs benignity."[25] However, Dr. Chernyak's 2018 publication notes, "LI-RADS defines

[23] Chernyak Dep. 49:6-11, 51:19-52:1.
[24] Chernyak Dep. 261:2-9, 270:1-7.
[25] Chernyak Report at 3 (emphasis added).

eight unique diagnostic categories based on imaging appearance that reflect the probability of HCC or malignancy."[26] Dr. Chernyak's 2018 publication noting eight categories is the only source Dr. Chernyak cited in her expert report to support her contention that there are only seven categories.[27] The LI-RADS core guidance document similarly lists eight diagnostic categories.[28] Dr. Chernyak admitted that the category she left out of her expert report was LR-NC (noncategorizable), because "it is not relevant."[29] Dr. Chernyak then testified that you apply LR-NC, "if all post-contrast phases were not done".[30] The delayed phase, which is missing from Mr. Roberts' 2016 CT, is a post-contrast phase. Mr. Roberts' 2016 CT should have been categorized as LR-NC, as it was missing the required phases. Dr. Chernyak's intentional omission of the LI-RADS category most applicable to Mr. Roberts' 2016 CT was misleading and further evidence of a conclusion driven expert report.

V. Dr. Chernyak's Application of LI-RADS is Unreliable

Dr. Chernyak's significant methodological lapses, as discussed above, render her LI-RADS-based opinions unreliable. As the court emphasized in *In re Paoli R.R. Yard PCB Litig.*, "any step that renders the analysis unreliable under the Daubert factors renders the expert's testimony inadmissible." 35 F.3d 717, 745 (3d Cir. 1994).

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[26] Chernyak Dep. 169:9-23.
[27] Chernyak Dep. 61:17-20.
[28] Chernyak Dep. 221:2-222:7.
[29] Chernyak Dep. 169:9-23.
[30] Chernyak Dep. 169:24-170:6.

Experts must demonstrate "good grounds" for each step in their analysis—not merely the conclusion. *Id.* at 742. This includes accounting for all relevant variables and adhering to standard protocols. By failing to verify cirrhosis in the medical record, applying LI-RADS without the required CT phases, and selectively omitting applicable diagnostic categories, Dr. Chernyak's opinions fall short of the "intellectual rigor that characterizes the practice of an expert in the relevant field." *Elcock v. Kmart Corp.*, 233 F.3d 734, 746 (3d Cir. 2000) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)).

Such litigation-driven deviation from established guidelines is precisely what courts have excluded under *Daubert*. See *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 594–95 (D.N.J. 2002), aff'd, 68 F. App'x 356 (3d Cir. 2003) (excluding expert who "unjustifiably extrapolated from an accepted premise to an unfounded conclusion" and failed to account for alternative explanations). Dr. Chernyak's unreliable methodology and failure to apply LI-RADS in accordance with her own criteria warrant exclusion of her related opinions under Rule 702.

VI. LI-RADS LR-3 Observations Are Indeterminate Findings

Even if Dr. Chernyak reliably and appropriately applied LI-RADS to Mr. Roberts' 2016 in coming to her opinon that Mr. Roberts had LR-3 lesions in his liver in 2016, LR-3 lesions are indeterminate observations and would not assist the trier

of fact.[31] As noted in Dr. Chernyak's report, "all LR-3 observations, about 33% are malignant."[32] Dr. Chernyak testified as follows when asked if she plans to tell the jury that Mr. Roberts might have had cancer in 2016:[33]

A. Mr. Roberts had lesions which had about 33 percent chance of having cancer in 2016. I cannot definitely rule out that the had cancer. I cannot definitely rule in. I can only provide probability based on imaging features.
Q. Would you argree that a 33 percent chance is equivalent to saying he might have cancer at the time in 2016?
A. If I were to use the certainty lexicon adopted by Memorial, it would be possible.
Q. Possible, not probable; correct?
A. Possible, yep.

When asked if there was an up to 68% chance of an LR-3 decreasing to an LR-1 (definitely benign) or LR-2 (probably benign), Dr. Chernyak testified:[34]

> "I have – we're *looking at probabilities* as they apply to the entire population and it comes to – so if you said – if, you know, any give LR-3 has a – then it's true. The problem is applying population probabilities to a particular patient is difficult, because it is a very specific lesion we're talking about. Because we **cannot say with any degree of reasonable certainty** that this particular lesion in Mr. Roberts' case would actually regress or stay the same, that is why this lesion requires a follow-up, because there's no way to say how this lesion will heave, because there is up to 24 percent chance of progression…"

[31] Chernyak Dep. 113:14-16, 231:17-19 ("LR-3 provides lowest certainty of malignancy and lowest certainty of benignity.").
[32] Chernyak Report at 5; *See also* Chernyak Dep. 69:5-21, 82:9-14.
[33] Chernyak Dep. 179:6-180:5, 64:2-5 ("About 33 percent of LI-RADS 3 lesions are HCCs, so there's a possibility that it was a small HCC at the time.").
[34] Chernyak Dep. 148:7-149:15 (emphasis added).

When asked if she could opine to a reasonable degree of medical certainity that Mr. Roberts had liver cancer in 2016, Dr. Chernyak testified, "What's a reasonable degree? ***Is 33 percent reasonable degree?*** I'm not sure what's reasonable degree."[35]

The unreliability and inaccuracy of LR-3 findings have also been identified as a "major unmet clinical need" by National Instiutes of Health.[36] Dr. Chernyak then admitted, "LI-RADS does not have reliable and accurate stratification of LR-3s."[37] Dr. Chernyak should be precluded from opining that Mr. Roberts had an LR-3 observation in his liver in 2016, as it is an indeterminate finding that would only serve to confuse the finder of fact.

VII. Reliable Methods Do Not Exist to Determine if an LR-3 Observation Will Progress to Cancer

After opining in her report that Mr. Roberts' "LR-3" had a 33% chance of being cancerous, Dr. Cherynak opined that "up to 60% of LR-3 observations progress to HCC within 48 months."[38] However, as discussed above, Dr. Cherynak also testified that an LR-3 had an up to 68% chance of decreaseing to an LR-1 (definitely beign) or LR-2 (probably benign) and only a 24% chance of progressing to cancer.[39] Dr. Chernyak clarified her in deposition that, "So, again, we don't have a good model

[35] Chernyak Dep. 82:22-83:6 (emphasis added).
[36] Chernyak Dep. 154:2-6.
[37] Chernyak Dep. 155:14-17.
[38] Chernyak Report at 5.
[39] Chernyak Dep. 148:7-149:15.

that identifies those LR-3s which will end up progressing to HCC."[40] Dr. Chernyak even explained, "there's a really significant need to say – to have some sort of reliable method to say, this lesion will progress, this lesion will not, and **right now we don't have that reliable method**. The only way – the only thing that we can do is say that this lesion meets criteria for LI-RADS 3".[41] Despite this, Dr. Chernyak plans to tell the jury "there's a chance" that the LR-3 lesions she observed progressed to cancer.[42] Even if Dr. Chernyak is allowed to testify that Mr. Roberts' had LR-3 observations in his liver in 2016, Dr. Chernyak should be precluded from opining that Mr. Roberts' LR-3 observation might have progressed to cancer by 2018, because Dr. Chernyak lacks a reliable methodology.

VIII. Dr. Chernyak's Opinion that 60% of LR-3s Progress to Cancer at 48 Months is Not Fit for this Case

Not only is Dr. Chernyak's opinion that 60% of LR-3s will progress to cancer at 48 months not reliable, it also does not fit the facts of this case. *See Oddi v Ford Motor Co.,* 234 F3d 136, 145-46 (3d Cir 2000) the expert tesimony must "fit" the case to assist the trier of fact.

There were only 28 months between Mr. Roberts' imaging in 2016 that did not detect any cancer and Mr. Roberts' imaging in 2018 that detcted a large amount

[40] Chernyak Dep. 144:18-20.
[41] Chernyak Dep. 154:13-19 (emphasis added).
[42] Chernyak Dep. 194:15-18.

of liver cancer.[43] Dr. Chernyak initially justified using the 48 month timepoint because, "That is the study that I quoted followed the lesions up to 48 months. That's the number that they've – they've reported."[44] Dr. Chernyak later conceded that the study also included a two year time point, which would have been more relevant to Mr. Roberts' case.[45] Dr. Chernyak then admitted that when applying the relevant time frame, an LR-3 would have only had "about 20 percent" chance of progressing to liver cancer.[46] Even if Dr. Chernyak is allowed to testify that Mr. Roberts' had LR-3 observations in his liver in 2016, Dr. Chernyak should be precluded from speculating as to the probability of the LR-3 oberservations progressing to cancer at irrelevant time points.

IX. LI-RADS Does Not Consider Patient Specific Factors

Dr. Chernyak exlained that LI-RADS is still evolving[47] and in the future the "most imporant thing is incorporating AI into some of the assessments to decrease some of the subjectivitity that is inherent right now".[48] Dr. Chernyak continued, laying out that the "grand vision" for LI-RADS is to have the AI model consider "patient factors" and "then providing a much more precise probability, so instead of

[43] Chernyak Dep. 85:22-86:2.
[44] Chernyak Dep. 85:16-21.
[45] Chernyak Dep. 87:24-88:4.
[46] Chernyak Dep. 88:10-24
[47] Chernyak Dep. 109:8-10.
[48] Chernyak Dep. 116:16-21.

saying, you know, Mr. --- you know, patient X has LI-RADS 3, which is 33 percent probability, it would say something like this patient has, I don't know, 52.3 percent probability of having HCC".[49] However, LI-RADS does not currently consider patient characteristics, though Dr. Chernyak hopes that eventually LI-RADS will consider patient specific factors.[50] The patient specific factors that Dr. Chernyak hopes that LI-RADS will one day consider includes age, sex, etiology, severity of liver disease, and quantitative biomarkers;[51] and even though Dr. Chernyak hopes that LI-RADS will eventually consider patient specific factors so that it will be more accurate, Dr. Chernyak did not review Mr. Roberts' medical records to identify his specific factors so that she could provide a more accurate opinion.[52] As such, Dr. Chernyak's opinion lacks the individualized foundation required for a specific causation experts' opinion to be reliable.

X. Dr. Chernyak's Tumor Volume Doubling Time Opinion is Not Fit for this Case and is Methodologically Unsound

In her report, Dr. Chernyak opines that "assuming a constant TVDT [Tumor Volume Doubling Time] of 3 months, it would take approximately 2 years and 8 months for a tumor to grow from 0.5 cm (the size of the LR-3 lesion observed in Segmetn VIII of the liver on April 2016 CT) to 5.8cm (the size of the LR-5 lesion

[49] Chernyak Dep. 116:22-117:20, 122:7-11.
[50] Chernyak Dep. 118:13-119:17.
[51] Chernyak Dep. 121:7-17.
[52] Chernyak Dep. 119:18-24.

observed in Segmetn VIII of the liver on the August 2018 MRI).[53] When confronted in deposition with the fact that there were 2 years and 4 months between Mr. Roberts' imaging, not 2 years and 8 months, Dr. Chernyak testified, "it's essentially statistically the same thing and it's not – it's not inconsistent with the statement."[54] Dr. Chernyak's baseless assertion that 2 years and 8 months is essentially stastically the same thing as 2 years and 4 months is without merit, as Dr. Chernyak was applying a 3 month tumor doubling time, which means the volume of Mr. Roberts' tumor was less than half its size at 2 years and 4 months compared to 2 years and 8 months. Dr. Chernyak's tumor volume doubling time opinion does not fit the facts of this case and is further evidence of a conclusion driven report.

Dr. Chernyak testified as follows when questioned about why she assumed 3 months[55] was the proper tumor volume doubling time to apply to Mr. Roberts' liver cancer[56]:

> Q. You note two-thirds of HCCs have a tumor volume doubling time of three months or longer; correct?
> A. Yes.
> *****

[53] Chernyak Report at 8; Of note, Dr Mahmud (defense hepatologist) also attempts to perform a tumor volume doubling time calculation with significantly different results (Mahmud Report at 34).
[54] Chernyak Dep. 196:20-197:3.
[55] Dr. Mahmud (defense hepatologist) testified that 3.9 months is the quickest tumor volume doubling time, and that Mr. Roberts tumor was likely slow-growing, with a tumor volume doubling time of 5.3 months (Mahmud Dep. 357:1-3, 411:22-412:16).
[56] Chernyak Dep. 184:19-22, 186:6-189:3.

Q. Would you agree that most HCCs take three months or longer to double in size?
A. The volume, the volume.
Q. It takes three months or longer for most HCCs to double volume; correct?
A. Yes.
Q. Then why in this case did you assume a tumor doubling volume time of three months?
A. Because that's the median?
Q. What do you mean?
A. Median?
Q. Yeah.
A. Means that it's in the center, the value's in the center.
Q. Isn't it only one-third of them are doubling at three months or less?
A. So the – again, the way that you – the six months – the six months of 50 percent size increase is based on three moths' tumor volume doubling time, so that's an accepted statement.
Q. But two thirds of HCCs wouldn't double that quickly; correct?
A. Two-thirds would – of HCCs would double at least this quickly – right, this quickly or longer, yes.
Q. And by longer, you mean slower, like four months or five months?
A. Yes.
Q. And then why – so why is it that you assumed the faster growth rate?
A. It's not fast. It's median. It's median – it's median – it's a median value that we assume which is used by – like, that's the value that's used to arrive at – at the threshold growth value of six months.
Q. How did you calculate this median?
A. It's just data.
Q. So you're applying the fastest one-third growth and you're saying that's the median?
A. That is the data that is used to arrive at the threshold growth, so that's the data that's used – that's the assumption that's used by UNOS, by LI-RADS. It's the threshold growth of six months.
Q. What is threshold growth?
A. Size increase, the longest dimension increase of 50 percent or greater.
Q. Do you need two images to determine threshold growth?
A. You need to have a study that is at least – that is done at least within six months prior—
Q. And do you have that with Mr. Roberts?
A. No.

Q. Then how can you apply threshold growth to Mr. Roberts?
A. I was providing the theoretical numbers.

Dr. Chernyak then conceded that her "experience with – you know, with longitudinal untreated HCC growth is limited."[57] When pushed on how she performed her tumor volume doubling calculation, Dr. Chernyak admitted that she entered entered "tumor volume doubling time is three months. Initial size is .5 centimeters. How long will it take to grow to this 5.8 centimeter" into ChatGPT (AI), which then applied a formula and gave Dr. Chernyak the answer of 2 years and 8 months.[58] The formula applied by ChatGPT does not appear anywhere in Dr. Chernyak's expert report.[59] When asked if she didn't have time to do the calculation in her expert report, Dr. Chernyak testifed, "No, as I'm not a mathematician, as I'm not a statistician, it was a – as I'm a radiologist, so I was focusing my energy on radiology".[60] When then asked if she could calculate the tumor's volume, Dr. Chernyak replied "I'm not a mathematician" and said that she would need to "ask Google."[61] Furthermore, Dr. Chernyak testified that in practice she does not use ChatGPT to calculate tumor volume doubling times.[62] ChatGPT is not peer-reviewed or a validated clinical source; therefore, Dr. Chernyak's tumor volume

[57] Chernyak Dep. 195:21-24.
[58] Chernyak Dep. 199:3-201:13.
[59] Chernyak Dep. 200:21-23.
[60] Chernyak Dep. 202:6-14.
[61] Chernyak Dep. 204:24-205:23.
[62] Chernyak Dep 202:22-203:1.

doubling time calculated by ChatGPT should be excluded. Additionally, Dr. Chernyak's incoherent basis for selecting a 3 month tumor volume doubling time, which Dr. Mahmud (Defense's hepatologist) explains is inapplicable to Mr. Roberts[63], further supports that Dr. Chernyak's expert report is conclusion driven.

XI. Dr. Chernyak's Opinion that Mr. Roberts' Liver Cancer Was Most Likely Caused by Cirrhosis is Conclusion Driven

Dr. Chernyak, a radiologist, intends to opine that Mr. Roberts' liver cancer was most likely caused by cirrhosis, despite Mr. Roberts not being diagnosed with cirrhosis prior to his cancer diagnosis.[64] Dr. Chernyak confirmed that she plans to give her opinion that Mr. Roberts' liver cancer was most likely caused by cirrhosis based off just his imaging[65]:

Q. But, again, you did nothing to look into Mr. Roberts' medical records other than his imaging; correct?
A. Correct.
Q. You didn't look into his pharmacy records; correct?
A. Correct.
Q. You don't know the total dose of NDMA that he was exposed to; correct?
A. Correct.
Q. And you've done no research on NDMA; correct?
A. Correct.
Q. But you want to go and tell the jury that the most likely cause of his HCC was cirrhosis?
A. Yes.
Q. Without – without considering any of his other risk factors, you want to go in and tell the jury that the most likely cause was cirrhosis for Mr.

[63] Mahmud Dep. 357:1-3, 411:22-412:16.
[64] Chernyak Report at 9.
[65] Chernyak Dep. 213:1-214:14.

Roberts' HCC?

A. HCC is the sixth most commonly diagnosed cancer in the world and 80 percent of HCCs occur in patients with cirrhosis.

Dr. Chernyak did not even consider Mr. Roberts' NDMA exposure as a potential cause of his liver cancer. Instead, Dr. Chernyak assumes that Mr. Roberts had cirrhosis prior to his liver cancer diagnosis, even though no treating physician ever diagnosed Mr. Roberts with cirrhosis prior to his liver cancer diagnosis. Dr. Chernyak then declares that Mr. Roberts' liver cancer must have been caused by cirrhosis. Dr. Chernyak's cancer causation opinion, like all other opinions in her expert report, is completely conclusion driven and unreliable.

CONCLUSION

For these reasons, the Court should exclude Dr. Chernyak from testifying at trial.

Respectfully submitted,

By: */s/ C. Brett Vaughn*

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CERTIFICATE OF SERVICE

I hereby certify that on May 22, 2025, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notifications of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ C. Brett Vaughn

C. Brett Vaughn, RN, BSN, JD